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Washington, DC 20004-2401

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,204,257

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 6,204,257, claims of which cover the human drug product LUSEDRA® (fospropofol disodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,424 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent No. 6,872,838 based on the regulatory review period for LUSEDRA® (fospropofol disodium).

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance, unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in U.S. Patent No. 6,872,838 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted, i.e., a certificate of extension will be issued to U.S. Patent No 6,204,257. In the absence of a request for reconsideration, and if U.S. Patent No. 6,204,257 is elected, the Director will issue to the applicant a certificate of extension, under seal, for a period of 1,424 days in U.S. Patent No. 6,204,257.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of April 5, 2010 (75 Fed. Reg. 17142). Under 35 U.S.C. § 156(c):

$$\text{Period of Extension} = \text{RRP} - \text{PGRRP} - \text{DD} - \tfrac{1}{2}(\text{TP} - \text{PGTP})^{1}$$

[1] Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i),

= 2,405 - 0 - 0 - ½ (1,962 - 0)
= 1,424 (3.9 years)

Since the regulatory review period began May 15, 2002, after the patent issued (March 20, 2001), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,204,257
Granted:	March 20, 2001
Original Expiration Date[2]:	August 7, 2018
Applicant:	Valentino J. Stella et al.
Owner of Record:	University of Kansas
Title:	Water Soluble Prodrugs of Hindered Alcohols
Product Trade Name:	LUSEDRA® (fospropofol disodium)
Term Extended:	1,424 days
Expiration Date of Extension:	July 1, 2022

(3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of ½ (TP - PGTP).

[2]Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: LUSEDRA® (fospropofol disodium)
Docket No.: FDA-2009-E-0202